

MAY - 8 1998



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

J. Trevor Lumb
Pfizer Inc.
Patent Department
235 East 42nd Street
New York, NY 10017-5755

Re: Patent Term Extension
Application for
U.S. Patent No. 5,089,480

#30

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,089,480, which claims the animal drug product DECTOMAX (doramectin), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 527 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 527 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 11, 1997 (62 Fed. Reg. 6263). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,695 - 1,210) + 141 \\ &= 884 \text{ days}\end{aligned}$$

Since the regulatory review period began October 26, 1988, before the patent issued (February 18, 1992), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From October 26, 1988 to February 18, 1992 is 1,210 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 884 days, would extend the patent from February 18, 2009 (35 U.S.C. § 154) to July 22, 2011, which is beyond the 14-year limit (the approval date is July 30, 2010, thus the 14 year limit is July 30, 2010). The period of extension is thus limited to July 30, 2010, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the

patent from its original expiration date, February 18, 2009, to and including July 30, 2010, or 527 days.

The limitations of 35 U.S.C. § 156 (g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,089,480
Granted:	February 18, 1992
Original Expiration Date ¹ :	February 18, 2009
Applicant:	Stephen P. Gibson, et al.
Owner of Record:	Pfizer Inc.
Title:	Antiparasitic Agents
Classification:	514/30
Product Trade Name:	DECTOMAX (doramectin)
Term Extended:	527 days
Expiration Date of Extension:	July 30, 2010

Any correspondence with respect to this matter should be addressed as follows:

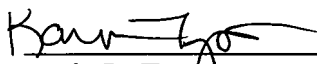
By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

¹Subject to the provisions of 35 U.S.C. § 41(b).

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: DECTOMAX (doramectin)
FDA Docket No.: 96E-0387